

In re Patent Application of
Saltiel
Serial No. 10/649,287
Filed 08/27/2003

REMARKS

Applicant appreciates the Examiner's continuing care in reviewing the application and has amended the claims to address the Examiner's concerns. Applicant also appreciates the Examiner's withdrawal of many of the previous rejections. Additionally, Applicant provides the following comments in support of the patentability of the pending claims. The amendments and remarks focus on the independent claims, since if these are found to be patentable, so will their respective dependent claims which add further distinguishing features to the claimed invention.

Claim 11 Is Patentable Over The Stevens Reference

On page 4 of the Office action, the Examiner rejects independent claim 11 as being obvious and unpatentable under Section 103(a) in view of the reference by Stevens (US Patent No. 4,686,023). This rejection is based on the Examiner's concern regarding the terms "substantially no photosynthesizer" as recited in this claim.

Applicant recognizes that the Examiner's concern could be addressed by language reciting a composition "consisting of." Such an amendment, however, would result in claims with little scope of protection, as a competitor could easily design around the claimed invention by including some small amount of an insignificant ingredient, rendering any resulting patent substantially meaningless (pun intended).

With that in mind, Applicant has amended claim 11 to recite "a reaction mixture consisting essentially of tachysterol" and the language "substantially no photosynthesizer" has been deleted from the claim. As interpreted under current case law, the language "consisting essentially of" should leave the claim open for the inclusion of only unspecified ingredients that do not "materially affect the basic and novel characteristics of the claimed composition." *Dow Chem. Co. v. American Cyanamid Co.*, 615 F.Supp. 471, 484, 229 U.S.P.Q. 171, 189 (E.D. La. 1985); *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*,

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750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). Accordingly, Applicant believes that while the claim language limits the contents of the reaction mixture to tachysterol, a court would take the view that small, insignificant amounts of other materials may also be present, as long as they do not materially affect the basic and novel characteristics of the claimed process. For those reasons, Applicant is hopeful that the Examiner will agree that the amended claim language avoids the concern regarding the photosensitizer, while preserving sufficient claim scope to provide meaningful protection for the invention.

The Invention Of Claims 1 And 18 Is Nonobvious Over The Malatesta Reference

The Examiner has rejected claims 1 (at page 7, paragraph VI) and 18 (at page 9, paragraph XII) under Section 103(a) as obvious and unpatentable in view of the Malatesta reference (US Patent No. 4,388,242). In this regard, the Examiner questions whether the compounds Lumi and Pre are the same as HOLumi and HOPre, as shown in FIG. 8.

Undersigned counsel has obtained the following information from Applicant which confirms that, for purposes of the invention, Lumi and Pre are functionally the same as HOLumi and HOPre. The following excerpt was provided by Applicant. If the Examiner believes a formal declaration should be submitted, Applicant would be pleased to do so.

Page 7, paragraph VI, line 14. The remote substitution of the hydroxy group at the 25 position of the alkyl side chain does not affect the chromophores (light absorbing diene and triene moieties) in Pro, Pre, Lumi, and Tachy (compare spectra in Fig. 8 for the 25-OH derivatives with spectra in references (a) Braun, M.; Fuß, W.; Kompa, K. L.; Wolfrum, J. J. Photochem. Photobiol. A: Chem. 1991, 61, 15-26; (b) Oppenländer, T.; Hennig, T. Chem. Ing.-Tech. 1995, 67, 594-597; and (c) Gliesing, S.; Reichenbächer, M.;

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Ilge, H.-D.; Faßler, D, E. J. Pract. Chem. 1987, 329, 311-320. These references were given as 13 (c), 15 (c) and 16 (d) in the 2003 J. Am. Chem. Soc. communication (Saltiel, J.; Cires, E.; Turek, A. "Conformer-Specific Photoconversion of 25-Hydroxytachysterol to 25-Hydroxyprevitamin D3: Role in the Production of Vitamin Ds" J. Am. Chem. Soc. 2003, 125, 2866-2867.) that was submitted to the Examiner. With respect to light absorption and photochemical response, the Lumi and Pre can be considered the same as HOLumi and HOPre. We did not claim zero absorption for these derivatives at 313 nm. What we claim is that Tachy (or HOTachy) absorbs much more strongly at 313 nm than either Lumi (or HOLumi) or Pre (or HOPre). Examination of our Figure 8 (for the HO derivatives) or the Figures in the references cited above (without the HO substituent) bears this out.

The Examiner has previously recognized that Malatesta teaches irradiating a reaction mixture in a second irradiation step with light having a wavelength of between 330-360 nm (see at Malatesta, column 1, lines 58-65). As shown in Applicant's FIG. 8, all of the compounds of interest in the process of making vitamin D have zero or near-zero absorption of energy above 330 nm, so that the Malatesta process is highly inefficient. Applicant points out that "the Malatesta reference fails to teach absorption at wavelengths below 330 nm in the second irradiation step." Thus, Malatesta fails to teach absorption at wavelengths below 330 nm in the second irradiation step and doesn't even recognize that irradiation below that wavelength can be advantageously employed in synthesizing vitamin D. Malatesta, therefore, cannot make the claimed invention obvious. Applicant, on that basis, respectfully requests that the obviousness rejections of claims 1 and 18 be withdrawn.

The Invention Of Claim 6 Is Patentable Over The Cited References

At page 13 of the Office action the Examiner also rejects independent claim 6 under Section 103(a) as unpatentable and obvious in view of the reference by Malatesta. The Examiner expresses the view that since Malatesta teaches irradiation in the second step at a wavelength of between 330-360 nm, claim 6 which recites irradiation at a wavelength of less than 330 nm cannot be considered patentable as it represents a difference of only 1 nm.

Applicant is somewhat puzzled by the Examiner's position. Respectfully, since Malatesta provides no teaching, guidance or suggestion of any kind indicating to the skilled that irradiation below 330 nm could be effective in the second step of vitamin D synthesis, it should not matter whether the claimed invention is only 1 nm apart from the range given in the cited reference. Applicant's FIG. 8 supports claiming up to just less than 330 nm.

The *prima facie* case of obviousness has not been established against claim 6 on the basis of the Malatesta reference. In order to make the *prima facie* case, the Examiner must establish three elements (MPEP §2143):

- 1) that the prior art contains a suggestion or motivation to combine the cited references in such a way as to achieve the claimed invention;
- 2) that one skilled in the art at the time the invention was made would have reasonably expected the claimed invention to work; and
- 3) that the combination must teach or suggest all the claim limitations, that is, that the combination produces the claimed invention.

It is clear that Malatesta does not teach or suggest a second step including irradiation below 330 nm. Furthermore, as an inventor, Malatesta would be considered one of above average skill in the art, more than just ordinary skill, yet he did not recognize the presently claimed invention. None of the three required elements of the *prima facie* case can then be established against claim 6 by the Malatesta reference.

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Since no *prima facie* case has been established, Applicant is not required to rebut same by providing evidence of criticality in his claimed range. Accordingly, Applicant respectfully requests that the obviousness rejection of claim 6 be withdrawn as well.

The Claim Objections Have Been Addressed

Applicant has amended the language of claims 21-23 and 27-29 as suggested by the Examiner to address all the claim objections.

Conclusion

Applicant has amended the claims to address all of the Examiner's concerns and has shown that they patentably define the invention over the cited references. Since the independent claims should now be patentable, so should their respective dependent claims which add yet further distinguishing features to the claimed invention. For those reasons, Applicant respectfully requests that the Examiner allow the claims and pass the application to issue. If the further processing of the application could be facilitated through a telephone conference between the Examiner and the undersigned, the Examiner is respectfully requested to telephone the undersigned.

Respectfully submitted,



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